

K051464

JUN 24 2005

PLANMECA

ENCLOSURE 12

P. 12-1

510K) SUMMARY

DATE

May 27, 2005

PRODUCT, CLASSIFICATION NAME

Trade name: Planmeca Promax

Common name: Panoramic x-ray system with cephalostat

Classification: 76 EHD, Class II

Regulation number: 872.1800

MANUFACTURER

Planmeca Oy

Asentajankatu 6

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Contact person: Lars Moring

UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)

Planmeca USA Inc.

100 North Gary Avenue, Suite A

Roselle, IL 60172

Phone: (630) 529 2300

Fax: (630) 529 1929

Contact person : Bob Pienkowski

INTENDED USE

Planmeca Promax, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device can be equipped with accessories to fulfil different diagnostic needs. In digital configuration the images are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer.

PRODUCT DESCRIPTION

The Planmeca Promax is a conventional panoramic x-ray system utilizing either films and cassettes or digital imaging. The product can be equipped with a cephalostat. The product modification includes a new DEC (Dynamic Exposure Control) system, which is designed to be used in digital imaging, in both panoramic and cephalostat modes, and replaces the old AEC system used.

SUBSTANTIAL EQUIVALENCE

We consider this product modification including a new DEC (Dynamic Exposure Control) system to be similar in design, composition and function to the following devices introduced into commercial distribution after May 28, 1976:

- # K011619 Planmeca Promax
- # K000163 PM 2002 Proline with AEC

The comparison of characteristics supports substantial equivalence. Planmeca Promax with DEC is as safe and effective as the predicate devices.



JUN 24 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bob Pienkowski
Managing Director
Planmeca USA, Inc.
100 North Gary Avenue, Suite A
ROSELLE IL 60172

Re: K051464
Trade/Device Name: Planmeca Promax with DEC
(Dynamic Exposure Control)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source
x-ray system
Regulatory Class: II
Product Code: EHD and MUH
Dated: May 27, 2005
Received: June 3, 2005

Dear Mr. Pienkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



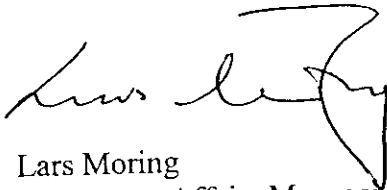
Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE


Planmeca Promax, panoramic x-ray imaging system with Cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device can be equipped with accessories to fulfil different diagnostic needs. In digital configuration the images are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer.

Helsinki, May 27, 2005



Lars Moring
Regulatory Affairs Manager
Planmeca Oy

Prescription Use ☒


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number 12051464